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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,458	05/16/2006	Maria Antonia Vitiello	PRD2091US-PCT	3414

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
RIGGS II, LARRY D	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,458	VITIELLO ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-26 and 32-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08 May 2007, 17 December 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 27-31, in the reply filed on 22 January 2008 is acknowledged.

Claims 1-26 and 32-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 January 2008.

Status of Claims

Claims 1-44 are currently pending. Claims 1-26 and 32-44 are withdrawn from consideration. Claims 27-31 are examined on the merits.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, (see specification, page 44, second paragraph). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Objections

Claim 27 is objected to because of the following informalities:

Step a) provides a repetition of the limitation "a pathogen species" in line 3. Examiner suggests removal of one copy of said limitation for grammatical correctness. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 in line 5 of step a) and claim 29 in line 2, recite the limitation “the model system”. There is insufficient antecedent basis for the limitation. Claim 27 only refers to developing experimental animals in line 1 of step a).

Claim 27 recites the limitation “the scores” in line 1 of step e) and “the score” in line 4 of step e). There is insufficient antecedent basis for these limitations.

Claim 27 recites the limitation “the biological sample” in line 4 of step e). There is no clear antecedent basis for the limitation. Step c) provided multiple biological samples from the experimental and control animals, in line 1, and it would be unclear which biological sample the limitation in step e) refers.

Claim 31 recites the limitation “administering an antibiotic to the animals” in lines 1-2. The metes and bounds of the limitation are unclear for the following reasons: What’s the relationship of this step with other steps, i.e. when is the antibiotic

administered in relation with the other steps? What is the role of this step in the invention? If the administering of the antibiotic is in addition to the test compound, then one skilled in the art would not be clear whether the scores would be affected by the antibiotic and how the scores could still be used for the test compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Bellinger-Kawahara et al., (US 6,964,856) in view of Laudes et al., (Am. J. Pathology, 2002, 160(5), 1867-1875) and further in view of Anderson et al., (US Pat. Pub. 2003/0194752).

The instant claims 27-31 provide a method of evaluating a test compound for treating sepsis syndrome, comprising:

(a) developing experimental animals modeling sepsis syndrome, comprising infecting experimental immunocompromised animals and control immunocompromised animals of the same species with a pathogen species capable of causing sepsis in the animal species, wherein the survival rate of immunocompromised infected animals in the model system is 10-90%;

(b) administering a test compound to the experimental animals;

(c) obtaining biological samples from the experimental and control animals at a selected timepoint following infection;

(d) measuring the amounts of a plurality of analytes in the biological samples; and

(e) determining the scores for the experimental and control animals using a discrimination function for the animal species; whereby if the test compound is determined to be effective in causing a statistically significant change in the score for

the biological sample compared to the score for the control animals, the test compound is a candidate drug for treating sepsis syndrome.

Regarding claim 27, Bellinger-Kawahara et al. shows a method of evaluating a test compound for treating sepsis by infecting experimental and control immunocompromised animals, with a pathogen capable of causing sepsis, wherein the survival rate of the infected animal was 39%, then administering the test drug to the experimental animals, a level of reporter in the experimental and control animals is measured at a select time interval after onset of sepsis, and selecting the test drug as a candidate drug for treating sepsis if the test drug is effective to cause a statistically-significant reduction in the level of reporter in the experimental animals compared with the control animals, (see abstract; column 2, lines 51-67; column 8, lines 20-56; column 12, line 54 – column 13, line 10; column 17, line 40 – column 18, line 38; Table 3).

Bellinger-Kawahara et al. does not show (c) obtaining biological samples from the experimental and control animals of the same species, at a selected timepoint following infection; (d) measuring the amounts of a plurality of analytes in the biological samples; and part of step (e), determining the scores for the experimental and control animals using a discrimination function for the animal species.

Laudes et al. shows obtaining samples from experimental and control animals of the same species, (see page 1868, right column, paragraphs 2-3) and measured the amounts of analytes, such as APTT, PT, platelet counts and fibrinogen levels, etc., at selected time points of 12, 24 and 36 hours, (See figures 2-8).

Bellinger-Kawahara et al. and Laudes et al. do not show determining scores for the experimental and control animals using a discrimination function.

Anderson et al. shows a discriminate model in which a score is computed for each patient, wherein the score is a linear function of the measured variables, and scores below a threshold are predicted to belong to on group and scores above the threshold are predicted to belong to another group, such as patients that progress to sepsis and patients that never progress to sepsis, (see paragraphs [0058], [0171]; Figure 1).

Regarding claims 28 and 30, Bellinger-Kawahara et al. shows that any test compound may encompass any compound or substance whose efficacy can be evaluated using the test animals and methods of the present invention, (see column 5, lines 4-15).

Regarding claim 29, Bellinger-Kawahara et al. shows 39% survival rate of immunocompromised infected animals, (see column 8, lines 20-56, column 17, line 40 – column 18, line 38; Table 3).

Regarding claim 31, Laudes et al. shows anti-C5a immunoglobulin, purified and precipitating the peptide of rat C5a, (page 1868, left column, first paragraph), wherein the purified anti-C5a immunoglobulin is administered to the animals, (see page 1869, left column, last paragraph – right column; Figures 2 and 3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of evaluating a test compound for treating sepsis by Bellinger-Kawahara et al. with the method of analysis and treatment of sepsis by

Laudes et al. and the model of discriminate analysis and classification by Anderson et al. because the classification model, that enables prediction of patients entering sepsis, combined with the analysis and administering of anti-C5a as an effective treatment of sepsis, would allow accurate predictions of whether animals will likely suffer sepsis and effectively treat the sepsis, (see Bellinger-Kawahara et al., column 1, lines, 47-52).

Conclusion

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631

/Shubo (Joe) Zhou/
Shubo (Joe) Zhou, Ph.D.
Primary Examiner